CTRNet Standard Operating Procedure Sample Shipping and Transportation			
SOP Number:	09.001	Version:	e2.1
Supersedes:	9.1.001 e1.0	Category:	Materials Request and Release

Approved By:	CTRNet Management Group (CMG)	14-Nov-2013
	Per: Brent Schacter	28-June-2012

1.0 PURPOSE

During the operation of the tissue biobank, samples will require shipping to different locations to meet the needs of users and for quality control purposes. Human Biological Materials (HBMs) are a precious resource. During the shipping process, care should be taken to protect and maintain sample integrity.

2.0 SCOPE

This standard operating procedure (SOP) outlines processes for shipping samples within Canada and internationally. The SOP specifies considerations that should be followed to ensure appropriate packaging and shipping of the samples.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

Note: When adopting this SOP for local use please reference CTRNet.

3.1 *CTRNet Policy: POL 6 Material Release*
3.2 *CTRNet Policy: POL 5 Records and Documentation*
3.3 *CTRNet Policy: POL 2 Ethics*
3.4 *CTRNet Policy: POL 4 Privacy and Security*
3.5 *CTRNet Policy: POL 7 Material and Information Handling*
3.6 *CTRNet Standard Operating Procedure: SOP 09.004 Material Request and Release*

4.0 ROLES AND RESPONSIBILITIES

The SOP applies to all personnel from CTRNet member biobanks who are involved in the shipping or receiving of samples.

Tumour Biobank Personnel	**Responsibility/Role**
Tumour Biobank Coordinator/Manager	Reviews request, coordinates sample release, ships sample

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

Materials and Equipment	Materials and Equipment (Site Specific)
Shipping waybill	
Proforma invoice	

6.0 DEFINITIONS

See the CTRNet Program Glossary: http://www.ctrnet.ca/glossary

7.0 PROCEDURES

The regional tumour biobanks and the directorate of the regional tumour biobanks manage the distribution of samples. Collection centers must only ship samples to qualified/approved researchers or to a designated third party laboratory for quality control analysis. The shipping process should only be initiated after obtaining written approval from the Director or designate of the regional biobank.
An established and tested shipping procedure is essential, as inadequate shipping procedures may lead to the loss of the samples and additional costs for repeat shipments.

The safe and legal transport of patient specimens is based on the following mandated activities:

a. Classification and naming of the material to be shipped,
b. Selection of packaging that will contain and protect the contents if the package is damaged,
c. Packing the shipment correctly,
d. Placing appropriate markings and labels onto the outer package,
e. Documenting relevant aspects of each package and its contents, and
f. Training individuals about the requirements for appropriate packaging and shipping of diagnostic specimens and infectious substances.

7.1 Appropriate Packaging and Shipping Conditions

7.1.1 Packaging must be appropriate for the transportation of perishable goods. Contents of the package may be categorized as being dangerous or biohazardous and so packaging must conform to transportation regulations. Consult www.iata.org for appropriate labelling and packaging required.

7.1.2 The International Air Transport Association (IATA) has defined a “patient specimen” as material collected directly from human or animals for diagnostic, treatment, prevention, investigational or research purposes. Patient specimens have to be categorized as Category A, Category B or Exempt Specimens.

7.1.3 Biobank personnel who will be responsible for categorizing material to be shipped must be: 1) trained in the transportation of dangerous goods; and 2) knowledgeable regarding the material and its likelihood to contain infectious substances (e.g., if shipping Formalin-fixed paraffin-embedded tissue then infectious substances are inactivated). Once the material to be shipped is categorized, all packaging, labeling and documentation must reflect the same

requirements – any differences in categorization between the waybill and commercial invoice may result in rejection or delay of the shipment.

7.1.4 A Category A substance is "an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, or life-threatening or fatal disease to otherwise healthy humans or animals".

7.1.5 A Category B substance is "an infectious substance which does not meet the criteria for inclusion in Category A". Typical clinical or patient specimens being shipped for routine culturing or other testing for a non-Category A infectious microorganism or suspected of containing a non-Category A infectious microorganism are examples of Category B substances.

7.1.6 Exempt human or animal specimens are those for which there is "minimal likelihood there are pathogens present".

7.1.7 Ship all frozen products in cryovials and frozen sections in slide shippers. This can be done on dry ice or in dry-shippers on liquid nitrogen. Dry ice is classified as a dangerous substance and needs to be sent in a double insulated shipper (styrofoam container in fitted cardboard box). Dry ice must NEVER be placed into a tightly sealed container (explosion hazard); the packaging must allow the release of CO_2.

7.1.8 Ship all refrigerated products on frozen gel packs in insulated shippers.

7.1.9 Ship paraffin blocks and slides with paraffin sections at room temperature. In summer weather or if high temperatures are anticipated, consideration should be given to including a cooling pack in the shipment.

7.1.10 To prevent damage during shipping and ensure leak-proof conditions, cryovials must be inserted in cardboard or plastic vial shippers. Glass slides must be inserted in slide shipping cassettes to prevent breakage and damage.

7.1.11 The quantity of samples to be shipped will affect the size of the packaging. Add sufficient refrigerant to maintain desired temperature throughout the shipping cycle. Use sufficient dry ice to ensure that the sample will remain frozen even if delayed in transit for 48-72 hours.

7.1.12 Tape and seal the packaging securely to prevent condensation of refrigerant and provide additional security for the contents.

7.1.13 Affix appropriate labels required to comply with shipping regulations and to ensure timely and proper shipping protocol. (e.g., dry ice declaration sticker, “Keep Frozen” sticker etc).

7.1.14 Before use, validate packaging to make sure it is able to maintain appropriate conditions of temperature, humidity, light sensitivity, structural quality and spill containment if relevant.

7.2 Appropriate Supporting Documentation

7.2.1 Contact the courier to establish what supporting documentation is needed to ship the sample to the specified destination. For international shipments, research any new regulations that may have been adopted or special permits that are needed for that destination.

7.2.2 Complete shippers Waybill and ProForma invoice (to provide contact information and to declare nature of contents to customs and regulatory agencies). For shipments to the United States, include a letter to the United States Department of Agriculture (USDA) to declare the presence or absence of possible contamination with any pathogenic agents if relevant.

7.2.3 Dry ice is a Class 9 dangerous good, and requires a dry ice checklist (http://www.iata.org/whatwedo/cargo/dgr/Documents/DG-Checklist-Dry-Ice-2013-EN.pdf).

7.3 Appropriate Courier

7.3.1 Identify and build a relationship with a courier that can consistently deliver frozen shipments within 24 hours.

7.3.2 To insure package is traceable use established couriers such as FedEx, Purolator or World Courier.

7.3.3 Assess and choose couriers for following characteristics:

- Reliability
- Experience with and ability to routinely ship biologics and HBMs to national and international destinations.
- Ability to provide online tracking of shipments.
- Knowledge about relevant transportation regulations and permits.
- Existence of established, standardized paperwork accompanying shipments.
- Efficient customer service ensuring that unforeseen delays and deviations are tracked and communicated to relevant personnel.
- Customer service agents capable of troubleshooting and expediting shipments in accordance with temperature and time sensitivity of the samples.
- Willingness to “top-up” dry ice in the package in the event of a delay in transit.

7.4 Shipping Log

7.4.1 Maintain a shipping log to record receipt and dissemination of shipments.

7.4.2 Track the following items:

a. Invoice number
b. Waybill number for tracking package
c. Recipient / source
d. Date received or shipped
e. Courier name and contact information
f. Sample description
g. Quantity shipped
h. Researchers name
i. Study name
j. Confirmation of delivery

7.5 Shipping Procedure

7.5.1 The day before the shipment is to go out, verify that there is an adequate stock of dry ice available.

7.5.2 Before scheduling a pick-up, assemble packaging material, refrigerants, samples to be shipped, accompanying documentation, shipping documentation and permits.

7.5.3 Contact shipper to schedule package pick-up.

7.5.4 Verify that all shipping information, contacts and required documents are accurate and complete.

7.5.5 It is optimal to specify to whose attention the shipment is being delivered. This measure should prevent the shipment from arriving and being held in the receiving department for too long.

7.5.6 Retrieve samples from storage and keep frozen on dry ice until packaged.

7.5.7 Use appropriate safety procedures when handling dry ice or when retrieving samples from liquid nitrogen containers.

7.5.8 Document sample retrieval in biobank database and complete shipping log according to established procedure.

7.5.9 Verify that samples match researcher's request.

7.5.10 Package samples as is appropriate (See section 7.1).

7.5.11 Contact (call or e-mail) consignee to provide them with Waybill number and inform them that package has been shipped. Give them an estimated delivery time so that they can anticipate arrival of the sample.

7.5.12 Track delivery (using the online tracking capability of the courier) to monitor shipment and expedite sample if delayed by Customs or regulatory agencies.

7.5.13 Timing of shipping (to prevent delays in-transit):

a. Schedule pick-up early in the day so that the package goes out on the earliest flight available.

b. Schedule pick-up for early in the week (Monday or Tuesday) to prevent delays in shipment or delivery due to the weekend schedules.

c. Do not ship just before a holiday long weekend as it usually translates into delays in transit.

d. Be aware of public holidays in the province or country of destination to plan for optimal shipping dates.

7.6 Test Shipment

In some situations, especially for extremely precious samples or when shipping to a new destination, biobanks may choose to send a test shipment with approximate characteristics of the actual shipment. This process may identify potential obstacles that could arise. It allows for corrective actions to be implemented, thus ensuring more successful shipment.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 Declaration of Helsinki
http://www.wma.net/en/30publications/10policies/b3/index.html

8.2 Tri-Council Policy Statement 2; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, December 2010.
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

8.3 Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics
http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420

8.4 International Air Transport Association (IATA)
http://www.iata.org/Pages/default.aspx

8.5 Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER).
http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositories

8.6 US National Biospecimen Network Blueprint
http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

8.7 National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999.
http://bioethics.georgetown.edu/nbac/hbm.pdf

8.8 Qualman, SJ. et al. Establishing a tumour bank: banking, informatics and ethics. Br. J. Cancer (2004). 90-1115-1119.

8.9 L.D. Gray and J.W. Snyder, (2006) Practical guidance to facilitate compliance with current international regulations that govern the packing and shipping of dangerous goods. Chapter 21 in Biological Safety, Principles and Prcatice, 4th edition, ed. D.O. Fleming and D.L. Hunt.

9.0 APPENDICES

None

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
TS 001.001	2005	JdSH	
9.1.001	2007	JdSH	Revised to make minor formatting changes and reviewed to reflect current practice at the member banks
9.1.001 e2.0	June 2012	CMG	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 1.0 – Deleted “and delicate” • Section 4.0-Deleted column 3 in table. • Section 7.1.6: Added para: “In summer weather…” • Revised 7.1.7
9.001 e2.1	Apr 2013	RB	7.2.3 – As per updated IATA requirement for shipping dry ice, use of ‘shipper’s declaration’ removed; use of ‘dry ice checklist’ added
9.001 e2.1	Oct 2013	RB	7.1.6 – As per updated TDG categorization, statement to always categorize as Exempt human specimens removed.